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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	Beiersdorf 540	Total Pages	
First Named Inventor or Application Identifier			
SEE ATTACHED APPENDIX			
Express Mail Label No.	EL295401143US		

10551 U.S. PRO
09/24/3016
02/02/99

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
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1. ☒ Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)
2. ☒ Specification [Total Pages 12]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the invention
 - Brief Summary of the invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 USC 113) [Total Sheets 1]
4. Oath or Declaration [Total Pages 2]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)
(Note Box 5 below)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference (useable if Box 4b is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☒ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement (when there is an assignee) ☐ Power of Attorney
10. ☐ English Translation Document (if applicable)
11. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
12. ☒ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. ☐ Small Entity ☐ Statement filed in prior application, Status still proper and desired
15. ☒ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☒ Other: Appendix

17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:
☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: _____

18. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label  or ☒ Correspondence address below
(Insert Customer No. or Attach bar code label here)

NAME	William C. Gerstenzang, Reg. No. 27,552				
	SPRUNG KRAMER SCHAEFER & BRISCOE				
ADDRESS	660 White Plains Road				
CITY	Tarrytown	STATE	New York	ZIP CODE	10591-5144
COUNTRY	USA	TELEPHONE	914-332-1700	FAX	914-332-1844

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Attorney Docket No. : Beiersdorf 540-WCG
: 1120-St-ar

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Dirk Lenz et al.
Serial No. : To Be Assigned
Filed : Herewith
For : OCCLUSIVE PLASTER
Art Unit : To Be Assigned
Examiner : To Be Assigned

February 2, 1999

Hon. Assistant Commissioner
for Patents
Washington, D. C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination, please amend the above-identified application as follows:

IN THE CLAIMS:

Claim 3, line 1, delete "Claims 1 and 2, characterized in that" and insert --Claim
1, wherein--.

Claim 4, line 1, delete "Claims 1 and 2, characterized in that" and insert --Claim
1, wherein--.

Claim 5, line 1, delete "Claims 1 to 4, characterized in that" and insert --Claim
1, wherein--.

Claim 6, line 1, delete "characterized in that" and insert --wherein--.

Claim 7, line 1, delete "one of Claims 1 to 6, characterized in that" and insert --
Claim 1, wherein--.

Claim 8, line 1, "one of Claims 1 to 7, characterized in that" and insert --
Claim 1, wherein--.

Claim 9, line 1, "one of Claims 1 to 8, characterized in that" and insert --
Claim 1, wherein--.

Claim 10, line 1, "one of Claims 1 to 9, characterized in that" and insert --
Claim 1, wherein--.

Claim 11, line 1, "one of Claims 1 to 10, characterized in that" and insert --
Claim 1, wherein--.

Claim 12, line 1, delete "one of Claims 1 to 11, characterized in that" and insert --
Claim 1, wherein--.

Claim 13, line 1 and 2, delete "at least one of the preceding claims" and insert --
Claim 1--;

line 11, delete "if appropriate" and insert --optionally--;

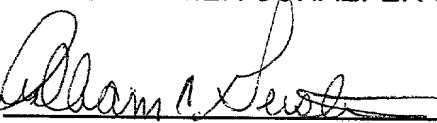
line 17, delete "if desired" and insert --optionally--;

line 18, delete "if desired" and insert --optionally--.

REMARKS

The foregoing amendment serves to eliminate multiple dependency and place the claims in compliance with U.S. practice.

Respectfully submitted,
SPRUNG KRAMER SCHAEFER & BRISCOE

By 
William C Gerstenzang
Reg. No. 27,552

WCG:lf

660 White Plains Road
Tarrytown, New York 10591-5144
(914) 332-1700
BEI546.2

Beiersdorf Aktiengesellschaft
Hamburg

Description

Occlusive plaster

The invention relates to a self-adhesive rapid dressing which is used as an occlusive plaster.

One of the uses of occlusive plasters is to treat strabism (squint), especially in children. For this treatment the occlusive plaster is stuck in particular over the leading, working eye of the afflicted patient in order to bring about fixation of the visually weak eye.

One example of a known and commercially available occlusive plaster is the "Elastopad ®" from Beiersdorf AG, Hamburg, Germany. The eye plaster consists of a transversely elastic woven viscose backing, a three-ply opaque light protection web, which is partially applied to the backing, and a zinc oxide-filled rubber composition as pressure-sensitive adhesive composition. This plaster features relatively good air permeability and water permeability but it is light-blocking (fully occlusive) only when sited over the eye with very great care. Further attributes of the plaster relate to the good fit, secure adhesion and conformability.

In addition there are further products in existence which generally employ a woven or nonwoven as the backing, which are punched out in the form of an occlusive plaster, and where there is - applied centrally - an absorbent pad which is provided with a more or less transparent liner.

However, the known plasters have a multiplicity of disadvantages. For instance, the desired full occlusiveness is often not ensured. Owing to the relatively

small and incomplete coverage of the backing with the light protection web, the lateral incidence of residual light is not ruled out, especially if the product is not sited precisely over the eye. This effect can be intensified further by the patient's movements and the associated shifting of the plaster.

Furthermore, the multi-ply structure of the occlusive plaster, composed of different materials, makes the production process complex and therefore relatively expensive.

DE 40 07 891 A1 discloses a backing material for medical purposes comprising a laminate having a first polymeric film layer, a second polymeric film layer which is produced on the first layer, and a third layer comprising a macroporous textile material which is embedded at least partially in the second layer. The first and second layers of this laminate can consist of polyurethane. The foaming of the individual layers, however, is not proposed.

The object of the invention was to provide an occlusive plaster which avoids the disadvantages of the prior art.

This object is achieved by an occlusive plaster characterized in accordance with the main claim. The subclaims relate to advantageous developments of the plaster and to a process for producing the occlusive plaster of the invention.

The invention relates accordingly to an occlusive plaster which consists of at least one layer of a foamed material and which is provided on the lower side with a skin-compatible self-adhesive layer.

To ensure occlusiveness adequately, the layer thickness of a one-layer occlusive plaster must be adequate - that is, at least 400 μm .

In one advantageous embodiment the occlusive plaster consists of a top layer made of a foamed material and an inner layer made from a foamed material, the latter layer being provided on the lower side with a skin-compatible self-adhesive layer.

It has also been found advantageous if an internal contour is printed in black on the top layer. Even with relatively low layer thicknesses of the top and/or inner layers, this contour, printed in black, ensures full occlusiveness.

In an alternative embodiment there is a black-coloured interlayer likewise formed of a foamed material between the top layer and the inner layer, over the entire area.

The foamed material employed preferably comprises PU, PP, PE or PVC foams, with particular preference being given to PU foam made of polyesterurethane.

The foamed material also preferably has a density in the dry state of from 0.03 to 0.8 g/cm³, in particular from 0.1 to 0.3 g/cm³.

In this case it has been found advantageous if the foam material has a layer thickness of from 0.2 to 2.0 mm, in particular from 0.3 to 0.8 mm. The smaller layer thicknesses in particular are achieved by calendering the foam material, causing it to undergo compression.

To both increase the foam density and decrease the cost of the material employed it is possible with advantage to add fillers, such as calcium carbonate, kaolin and/or alumina, to the foamed material.

To increase the mechanical stability in the lengthwise and transverse direction and to increase the tear propagation resistance of the foams, a layer of unfoamed PU can be applied to the top layer or a two-dimensional textile structure (nonwoven, knit, woven) can be embedded in the top layer.

Furthermore, an absorbent pad smaller than the adhesive area can be applied to the adhesive side of the inner layer, preferably in the middle of the backing material.

Finally, a further advantageous embodiment of the plaster is that in which the self-adhesive side is provided with at least one peelable cover sheet as a protective covering.

The inventive concept then embraces a process for producing an occlusive plaster, consisting of the following process steps.

The first step involves introducing the top layer, the inner layer and, if present, the interlayer in each case in a mixture of aqueous aliphatic dispersions of

polyesterurethanes.

A foaming agent (preferably ammonium stearate, Stokal products from Stockhausen) and a dye are added to each of the mixtures.

In addition to the black-coloured interlayer, preference is given here to a skin-coloured top layer and a white inner layer.

The respective mixtures are brought to the desired degree of foaming by blowing air into them.

The coating operation begins with foam for the top layer being coated out onto a release paper and then dried.

The release paper - or, to be more precise, the particular form of the surface of the release paper - causes the dried foam and/or the top layer to take on a particularly soft, silky appearance.

Where an interlayer is provided, the foam for the interlayer is coated out onto the dried top layer and then dried.

The foam for the inner layer is coated out in the same way as for the top layer and, if appropriate, the interlayer and is likewise dried.

To produce the actual occlusive plasters, the adhesive coating is applied first of all and then the occlusive plasters are punched out.

Optional operations include the application of an absorbent pad centrally to the inner layer, and the sealed enclosure of the individual plasters.

The occlusive plaster of the invention has a host of advantages over the prior art plasters.

The full occlusiveness required of the occlusive plaster can be realized optimally, in particular, in the case of the advantageous embodiment with the black-coloured interlayer. The entire area of the plaster is light-blocking or can be made so.

Top layer, inner layer and interlayer can be produced from a single material, which is very cost-effective and minimizes the complexity.

The conformability of the plaster and the softness of the surface are unsurpassed and are ideally suited to use on the eye.

The intention of the text below is to illustrate particularly advantageous embodiments of the occlusive plaster, on the basis of a number of examples, without thereby wishing unnecessarily to restrict the invention.

In Example 1 the occlusive plaster of the invention is elucidated further at the same time by means of Figure 1.

Example 1

The occlusive plaster produced was composed of a total of three PU foam plies, namely a skin-coloured top layer (applied weight 77 g/m^2) 1, a black-coloured interlayer 2 (applied weight 33 g/m^2) and a white-coloured inner layer 3 (applied weight 58 g/m^2).

The internal black interlayer was covered effectively on both sides by the external layers so as to avoid the passage of light through the black layer.

The individual foam coats consisted of a mixture of aqueous aliphatic dispersions of polyesterurethanes (Impranil grades, Bayer AG, Leverkusen, Germany) provided with a foaming agent (ammonium stearate, Stokal products, Stockhausen, Germany) and the respective dyes (brown, black, white) and were processed by blowing air into them to give a beaten foam having a density of 0.4 g/cm^3 .

On a coating unit with a shoe blade (coating bar) and a fan-type or radiative drier, the first beaten foam was applied to a release paper (Warren Stripkote) and knifed off at a coating-bar gap of between 0.5 and 0.7 mm. The foam was dried in a drying tunnel at a temperature increasing from 70 to 150°C in a plurality of zones over a length of 15 m.

The application of the second layer of beaten foam with the other colour took place directly onto the first PU foam, which had been dried beforehand. Subsequently, the third layer was applied to the second layer.

The result was a fixed assembly of the three foam layers which together had a thickness of 0.8 mm and a basis weight of 170 g/m^2 and showed absolute opacity in the region of visible light (400 to 700 nm). Furthermore, the material was permeable to air and extremely permeable to water vapour.

Specific values are given in Table 2.

An adhesive coating 4 was applied over the entire area of the inner layer 3, an absorbent pad 5 made from a nonwoven having been applied in turn centrally to the said coating 4. The contour of the plaster was adapted correspondingly to the contour of the orbit.

Example 2

In the same way as in Example 1 a multi-ply occlusion plaster was produced by coating with a beaten PU foam of equal density based on aliphatic polyesterurethanes (Impranil grades, Bayer AG, Leverkusen, Germany).

As a further layer on the top layer, a compact cover coat, rather than a foam (Impraperm grade, Bayer AG, Leverkusen, Germany) was applied with a basis weight of 11 g/m^2 .

This layer is intended to increase the mechanical stability in the lengthwise and transverse direction and the tear propagation resistance of the foams.

In this embodiment the black interlayer had a basis weight of 55 g/m^2 .

The amended embodiment showed markedly higher ultimate tensile strength in the lengthwise and transverse direction. The result was a (still) extremely good water vapour permeability but now without air permeability.

Example 3

The chosen starting material was a single-ply blown foam based on aromatic two-component polyurethanes (High-Solids grades, from Bayer, Leverkusen, Germany) with a basis weight of 250 g/m^2 and a thickness of 0.4 mm.

In comparison to the beaten foams based on aqueous aliphatic polyesterurethanes in accordance with Examples 1 and 2, the material showed a markedly higher tear strength in the lengthwise and transverse direction and a markedly higher density, as well as extremely good water vapour permeability.

The tables depicted below give an overview once more of the construction of the occlusive plasters designed in accordance with the invention as in the preceding examples. The second table gives information on the physical properties of the occlusive plasters.

Construction	Example 1	Example 2	Example 3
Skin-coloured top coat	---	11 g/sq. m	---
Skin-coloured top layer	77 g/m ²	108 g/m ²	250 g/m ²
Black interlayer	33 g/m ²	55 g/m ²	---
White inner layer	58 g/m ²	74 g/m ²	---

Table 1: Construction of the occlusive plasters of Examples 1 to 3

Method	Example 1	Example 2	Example 3
Basis weight	170 g/m ²	250 g/m ²	250 g/m ²
Thickness	0.8 mm	1.1 mm	0.4 mm
Density (dried state)	0.212 g/cm ³	0.220 g/cm ³	0.625 g/cm ³
Ultimate tensile strength lengthwise (DIN EN ISO 527)	6.8 N/cm	9 N/cm	11 N/cm

Elongation at ultimate tensile strength lengthwise (DIN EN ISO 527)	400 %	410 %	400 %
Ultimate tensile strength transverse (DIN EN ISO 527)	6.3 N/cm	12.5 N/cm	11 N/cm
Elongation at ultimate tensile strength transverse (DIN EN ISO 527)	470 %	540 %	400 %
Air permeability Gurley densometer (Gurley, Troy Instruments, New York, USA)	40 cm ³ /(cm ² s)	---	---
Water vapour permeability Method based on DAB 10*)	5500 g/(m ² *24h)	2900 g/(m ² *24h)	1900 g/(m ² *24h)

Table 2: Physical properties of the occlusive plasters of Examples 1 to 3

*) A material sample is fastened tightly over a sample structure (specified in accordance with DAB [German Pharmacopoeia] 10) which is filled with 15 ml of water. The sample vessel is left in a climatically controlled cabinet at 37°C and 30% relative atmospheric humidity for 24 h and the water vapour permeability in g/(m²*24 h) is determined by back-weighing.

Claims

1. Occlusive plaster consisting of at least one layer of a foamed material which is provided on the lower side with a skin-compatible self-adhesive layer.
2. Occlusive plaster according to Claim 1, consisting of a top layer made of a foamed material and an inner layer made of a foamed material, the said inner layer being provided on the lower side with a skin-compatible self-adhesive layer.
3. Occlusive plaster according to Claims 1 and 2, characterized in that an internal contour is printed in black on the top layer.
4. Occlusive plaster according to Claims 1 and 2, characterized in that a black-coloured interlayer made of a foamed material is present between the top layer and the inner layer over the entire area.
5. Occlusive plaster according to Claims 1 to 4, characterized in that PU, PP, PE or PVC foams are employed as the foamed material.
6. Occlusive plaster according to Claim 5, characterized in that a polyesterurethane is employed as PU foam.
7. Occlusive plaster according to one of Claims 1 to 6, characterized in that the foamed material has a density in the dry state of from 0.03 to 0.8 g/cm³, in particular from 0.1 to 0.3 g/cm³.
8. Occlusive plaster according to one of Claims 1 to 7, characterized in that the foamed material has a layer thickness of from 0.2 to 2.0 mm, in particular from 0.3 to 0.8 mm.
9. Occlusive plaster according to one of Claims 1 to 8, characterized in that fillers, such as calcium carbonate, kaolin and/or alumina, are added to the foamed material.

10. Occlusive plaster according to one of Claims 1 to 9, characterized in that a layer of unfoamed PU is applied to the top layer or a two-dimensional textile structure (nonwoven, knit, woven) is embedded in the top layer.
11. Occlusive plaster according to one of Claims 1 to 10, characterized in that a wound pad smaller than the adhesion area is applied to the adhesive side of the inner layer.
12. Occlusive plaster according to one of Claims 1 to 11, characterized in that the self-adhesive side is provided with at least one peelable cover sheet as a protective covering.
13. Process for producing an occlusive plaster according to at least one of the preceding claims, consisting of the following process steps:
 - a) preparing the top layer, the inner layer and, if present, the interlayer in each case by introducing a mixture of aqueous aliphatic dispersions of polyesterurethanes,
 - b) adding a foaming agent and a dye to the respective mixture,
 - c) foaming the respective mixture to the desired degree of foaming by blowing air into it,
 - d) coating out the foam for the top layer onto a release paper, with subsequent drying,
 - e) if appropriate, coating out the foam for the interlayer onto the dried top layer, with subsequent drying,
 - f) coating out the inner layer on the top layer or interlayer, with subsequent drying,
 - g) applying the adhesive coating, with subsequent punching-out of the occlusive plasters,
 - h) if desired, applying an absorbent pad centrally to the inner layer,
 - i) if desired, sealingly enclosing the individual plasters.

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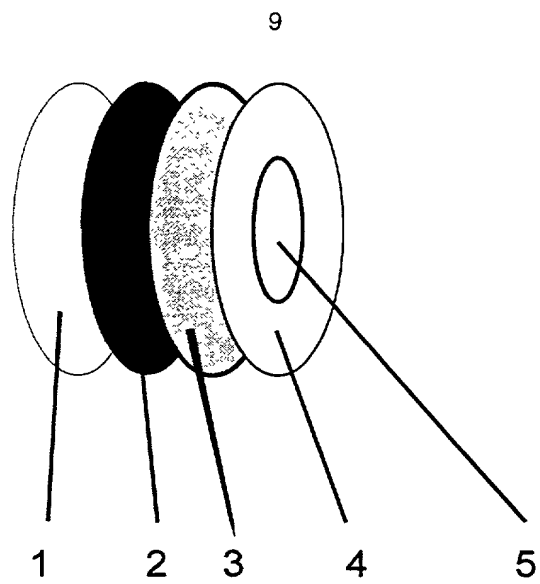


Figure 1

COMBINATION DECLARATION & POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled „**Occlusive plaster**“ the specification of which is attached hereto.

-OR-

was filed on _____ as

Application Serial No. _____ and was amended _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed
<u>198 04 665.0</u> (Number)	<u>Germany</u> (Country)	<u>06/02/1998</u> (Day/Month/Yr. Filed)	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
_____	_____	_____	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
(Number)	(Country)	(Day/Month/Yr. Filed)	

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

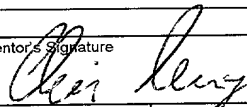
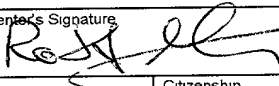
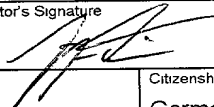
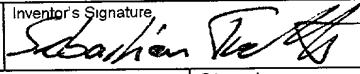
_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punished by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named Inventor, I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Arnold Sprung, Reg. No. 17,232; Nathaniel D. Kramer, Reg. No. 25,350; Ira J. Schaefer, Reg. No. 26,802, and Esther Steinhauer, Reg. No. 40,255 all of 120 White Plains Road, Tarrytown, New York 10591; Kurt G. Briscoe, Reg. No. 33,141; William C. Gerstenzang, Reg. No. 27,552; Paul J. Juettner, Reg. No. 20,974 of 660 White Plains Road, New York 10591, my attorneys with full power of substitution and revocation

Send Correspondence To: Sprung Kramer Schaefer & Briscoe 660 White Plains Road 4th Fl. Tarrytown, New York 10591-5144	Direct Telephone Calls To: (914) 332-1700
---	---

Full Name Of Sole or First Inventor Dr. Dirk Lenz	Inventor's Signature 	Date 9.12.98
Residence Contastraße 3, D-20253 Hamburg, Germany	Citizenship German	
Post Office Address Contastraße 3, D-20253 Hamburg, Germany		
Full Name Of Second Inventor Dr. Robert Mayan	Inventor's Signature 	Date 3.12.98
Residence Eckdahl 24, D-21614 Buxtehude, Germany	Citizenship German	
Post Office Address Eckdahl 24, D-21614 Buxtehude, Germany		
Full Name Of Third Inventor Jürgen Timm	Inventor's Signature 	Date 4th Dec. 98
Residence Vor der Heide 28, D-21218 Seevetal, Germany	Citizenship German	
Post Office Address Vor der Heide 28, D-21218 Seevetal, Germany		
Full Name Of Fourth Inventor Sebastian Trotter	Inventor's Signature 	Date 08.12.98
Residence Sanddornweg 4, D-21244 Buchholz, Germany	Citizenship German	
Post Office Address Sanddornweg 4, D-21244 Buchholz, Germany		
Full Name Of Fifth Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		
Full Name Of Sixth Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		
Full Name Of Seventh Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		

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